REMARKS

Favorable reconsideration of this application is respectfully requested in view of the following remarks.

The Official Action sets forth a rejection of Claims 11 and 12 based on the second paragraph of 35 U.S.C. § 112. It is said here that Claims 11 and 12 are indefinite because they depend from an apparatus claim, but recite various aspects of the method for producing the implantable tubular device. The Examiner's observation that Claims 11 and 12 define aspects related to the method of manufacturing the device is accurate. However, this does not render the claims indefinite. The second paragraph of 35 U.S.C. § 112 requires that the claims define the invention in a manner that would allow one ordinarily skilled in the art to understand the metes and bounds of the claimed invention. Claims 11 and 12 satisfy this requirement because the claim wording defines aspects associated with the manufacturing method that one of ordinary skill in the art would be able to readily understand. Also, Claims 11 and 12 further limit the device defined in independent Claim 1 in that Claims 11 and 12 define aspects of the manufacturing method for producing the claimed implantable device that distinguish the device from implantable devices manufactured in a completely different manner.

In light of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the indefiniteness rejection of Claims 11 and 12 based on the second paragraph of 35 U.S.C. § 112.

The Official Action sets forth a rejection of independent Claim 1 and various dependent claims on the basis of the disclosure contained in U.S. Patent No. 5,876,449 to *Starck et al.* To more clearly highlight differences between the claimed implantable device defined in independent Claim 1 and the disclosure contained in *Starck et al.*, Claim 1 has been amended to include the subject matter recited in Claim 8, and Claim 8 has been cancelled. In addition, Claim 1 has been amended to recite that the implantable device includes a plurality of deformable portions. Various dependent claims have been amended to ensure consistency with respect to the changes to independent Claim 1.

In addition, independent Claim 2 has been placed in independent form, and new Claims 20-31 are presented for consideration. Thus, the claims currently at issue are Claims 1-7 and 9-31, with Claims 1 and 2 being the only independent claims.

Independent Claim 1 defines that the implantable tubular device which is formed substantially tubular has a deformable portion formed on its peripheral surface. The deformable portion forms a predetermined angle with respect to the axial direction of the device and is more easily deformed compared with the remainder of the device. In addition, the deformable portion is formed in a plural number provided entirely on the implantable tubular device.

Starck et al. discloses a stent for transluminal implantation in hollow organs. The Official Action observes that the disclosed stent includes a deformable portion as illustrated in Figs. 4a and 4b of *Starck et al.* In the discussion of Figs. 4a and 4b beginning at the bottom of column 4, *Starck et al.* describes cut-outs 16 that are provided at the connection

locations 10 between two frame elements arranged adjacent each other in the circumferential direction of the tubular body. *Starck et al.* goes on to note that the cut-outs 16 can be positioned between two directly connected together boundary elements 5 as illustrated or can be provided between the boundary elements 5 and the V-shaped intermediate elements 13. Thus, *Starck et al.* specifically envisions providing the cut-outs in the connection locations. It is possible that the connection locations at which the cut-outs 16 disclosed in *Starck et al.* are provided may not be sufficiently flexible to pass relatively easily through the bent portion of a human, thus presenting possible difficulties during usage. In addition, a deformation hysteresis occurring when the stent is inserted into the human body can remain in the locations at which the cut-outs 16 are provided and so it is possible that the stent may stick in the bent portion of a human. The location of the cut-outs 16 at the connection locations 10 between two frame elements as described in *Starck et al.* is to be contrasted with the claimed implantable tubular device recited in Claim 1 in which the deformable portions are entirely on the implantable tubular device. The claimed implantable tubular device is not as susceptible to difficulties such as those mentioned above which might be attributable to the construction envisioned by *Starck et al.*

In light of at least the foregoing differences, it is submitted that Claim 1 is patentably distinguishable over the disclosure contained in *Starck et al.*

The other document relied upon in the Official Action to address features set forth in various dependent claims, U.S. Patent No. 5,788,979 to *Alt et al.*, does not make up for the deficiency pointed out above with respect to the disclosure contained in *Starck et al.*.

Accordingly, the combined disclosures contained in *Starck et al.* and *Alt et al.* would not have directed one to do that which is defined in independent Claim 1 as the invention.

Independent Claim 2 is also patentably distinguishable over the disclosure contained in *Starck et al.* Claim 2 defines that the implantable tubular device is comprised of a plurality of wavy annular members arranged in an axial direction of the device, with the wavy annular member being formed of a wavy element. Connecting portions connect the wavy annular members to each other in the axial direction of the device, and each of the wavy annular members has free bent portions not connected to the other wavy annular members. In addition, the implantable tubular device includes a deformable portion more easily deformable than the remainder of the device. The deformable portion is formed on one of the free bent portions of the wavy annular members so that the deformable portion crosses the wavy annular member. This positioning of the deformable portion on the free bent portion of a wavy annular member that is not connected to other wavy annular members clearly distinguishes over the disclosure contained in *Starck et al.* As noted above, *Starck et al.* describes providing cut-outs 16 at the connection locations between adjacent frame elements. It is thus submitted that independent Claim 2 is also patentably distinguishable over the disclosure contained in *Starck et al.*

The dependent claims define further distinguishing characteristics associated with the claimed implantable tubular device, but are nevertheless allowable at least by virtue of their dependence upon allowable independent claims.

In light of the foregoing, it is submitted that this application is in condition for allowance and such action is earnestly solicited.

Should any questions arise in connection with this application or should the Examiner believe that a telephone conference with the undersigned would be helpful in resolving any remaining issues pertaining to this application, the undersigned respectfully requests that he be contacted at the number indicated below.

Respectfully submitted,

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Attachment to Amendment dated November 5, 2002

Mark-up of Claims 1-3, 5-7, 9, 11, 12 and 16

1. (Amended) An implantable tubular device formed substantially tubular and having a deformable portion formed on a peripheral surface thereof, with said deformable portion forming a predetermined angle with respect to an axial direction of said device and being easy to deform in comparison with a remainder part of said device, said deformable portion being formed in a plural number, and said deformable portions being entirely on said tubular device.

2. (Amended) An implantable tubular device [according to claim 1, wherein said device has] formed substantially tubular and having a diameter so set that said device can be inserted into a lumen in a human body and capable of dilating radially upon application of a force acting radially outwardly from an interior of said tubular body,

said device comprising:

a plurality of wavy annular members each formed of a wavy element and arranged in an axial direction of said device; and

connection portions each connecting said wavy annular members to each other in the axial direction of said device;

wherein each of said wavy annular members has free bent portions not connected to other wavy annular members;

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Mark-up of Claims 1-3, 5-7, 9, 11, 12 and 16

a deformable portion forming a predetermined angle with respect to the axial direction of the device and more easily deformed than a remainder of the device;

said deformable portion being formed on [a] one of the free bent [portion thereof not connected to the other wavy annular members] portions in such a way that said deformable portion crosses said wavy annular member.

3. (Amended) An implantable device according to claim 1, wherein said deformable [portion consists of] portions include a groove formed on an inner surface of said device or on an outer surface thereof or on both said inner and outer surfaces thereof.

5. (Amended) An implantable device according to claim 1, wherein said deformable [portion forms] portions form an angle of 20 - 90° with the axial direction of said device.

6. (Amended) An implantable device according to claim 1, wherein said deformable [portion is formed in a plural number; and] portions are so formed that when said deformable [portion is] portions are prolonged, said deformable [portion] portions continuously [goes] go around a periphery of said device.

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Mark-up of Claims 1-3, 5-7, 9, 11, 12 and 16

7. (Amended) An implantable device according to claim 1, wherein said deformable [portion is] portions are so formed that when said deformable [portion is] portions are prolonged, a spiral is formed on the periphery of said device.

9. (Amended) An implantable device according to claim 1, wherein [said deformable portion is formed in a plural number and] an interval between said deformable portions in the axial direction of said device is 0.01 - 1mm.

11. (Amended) An implantable device according to claim 1, wherein said device is formed by [the step of] forming a spiral deformable portion-provided tubular body by connecting axially adjacent coiled wire members to each other directly or indirectly and [the step of] removing a portion of said tubular body other than a portion thereof which is to be formed as said device.

12. (Amended) An implantable device according to claim 1, wherein said device is formed by [the step of] forming an annular deformable portions-provided tubular body by directly or indirectly connecting ring members so disposed parallel to each other as to form a cylindrical shape and [the step of] removing a portion of said tubular body other than a portion thereof which is to be formed as said device.

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Mark-up of Claims 1-3, 5-7, 9, 11, 12 and 16

16. (Amended) An implantable device according to claim 1, wherein at least one part of an outer surface of said deformable [portion] portions is coated with a coating material made of a biocompatible material, a biodegradable material or a synthetic resin.